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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/519,826 | 09/14/2005 | Diego Walther | BB-123 | 3100 |

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| EXAMINER | |
|---|---|
| CHOWDHURY, IQBAL HOSSAIN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1652 | |

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/519,826 | WALTHER ET AL. | |
| | Examiner | Art Unit | |
| | Iqbal H. Chowdhury, Ph.D. | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Claims 1-21 and 24-28 are pending.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group, I claim(s) 1, 4-7, drawn to an isolated polynucleotide encoding a polypeptide tryptophan hydroxylase.

Group, II claim(s) 2-3, 25-27, drawn to isolated polypeptide tryptophan hydroxylase.

Group, III claim(s) 9, drawn to an antibody that binds to the polypeptide tryptophan hydroxylase.

Group, IV claim(s) 8, drawn to a method for producing antibody by using polypeptide tryptophan hydroxylase as antigen.

Group, V claim(s) 10-11, drawn to a method for isolating a compound that binds to a polypeptide tryptophan hydroxylase.

Group, VI claims 12-14, drawn to a method for treatment of a neuronal disease in a patient by modulating tryptophan hydroxylase activity.

Group, VII claim(s) 15-17, drawn to a method for determining the pharmacogenetic properties of a compound by administering the compound and determining the level of expression of tryptophan hydroxylase.

Group, VIII claims 18, drawn to a method for the treatment of diseases by administering polynucleotide sequence or polypeptide sequence.

Group, IX claim(s) 19, drawn to a method for diagnosing a neuronal disease by decreasing serotonin biosynthesis followed by detecting metabolite concentrations in CNS.

Group, X claim(s) 20 and 21, drawn to a method of identifying a protein by using nucleic acid or polypeptide by using Two-Hybrid System.

Group, XI claims 24, drawn to a method of modulating serotonin level by using nucleic acid or polypeptide by specific regulation of tryptophan hydroxylase activity.

Group, XII claims 28, drawn to a method of use of combination therapeutic composition for treating neuronal diseases.

For each inventions I-XII above, restriction to one of the following is also required under 35 U.S.C. 121 and 372. Therefore, election is required of one of inventions I-XII **and** one of inventions (A) – (C).

(A). protein of SEQ ID NO: 2 or a nucleic acid encoding SEQ ID NO: 2.

(B). protein of SEQ ID NO: 4 or a nucleic acid encoding SEQ ID NO: 4.

(C). protein of SEQ ID NO: 6 or a nucleic acid encoding SEQ ID NO: 6.

2. The inventions listed as Groups I - XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The polynucleotide encoding a polypeptide neuronal tryptophan hydroxylase of Group I, polypeptide neuronal tryptophan hydroxylase of Group II and antibody of Group III are each unrelated and chemically distinct entities. The only shared technical feature of these groups is that they all relate to polynucleotide encoding a polypeptide neuronal tryptophan hydroxylase. However, this shared technical feature is not a "special technical feature" as defined by PCT Rule 13.2 as it does not define a contribution over the art. According to the search report (PCT form 210), a DNA encoding a neuronal tryptophan hydroxylase is known in the art (WO/2002/17891, see IDS). Thus, a DNA encoding a neuronal tryptophan hydroxylase protein does not make contribution over the prior art.

3. The antibody of Group III does not share any "special technical feature" with Group I as the polynucleotides of Group I are neither made nor used by the antibody of Groups III.

4. The polynucleotides of Group I do not share any "special technical feature" with method of producing antibody of Group IV as the polynucleotide of Group I is neither made nor use by the method of Group IV.

5. A method of screening candidate therapeutic compound of Group V does not share any "special technical feature" with Group I as the polynucleotides of Group I are neither made nor used by the method of screening candidate therapeutic compound of Group V.

6. The protein of Group II does not share any "special technical feature" with methods of Group VI-IX as the polypeptide of Group II is neither made nor use by the methods of Group VI-IX.

7. The polynucleotides of Group I does not share any "special technical feature" with methods of Group IV-VII, IX and XII as the polynucleotide of Group I is neither made nor use by the methods of Group IV-VII, IX and XII.

8. The antibody of Group III does not share any "special technical feature" with methods of Group IV-XII as the antibody of Group III is neither made nor use by the methods of Group IV-XII.

10. The methods of Groups IV-XII do not have unity of invention with each other as each methods comprises unrelated steps, use different products and produce different effects.

11. The proteins of Group (A)-(C) having tryptophan hydroxylase activity, do not share any "special technical feature" among each other because they all represent structurally different polypeptides and polynucleotide encoding them but linked with each other having tryptophan hydroxylase activity. As mentioned above, a DNA encoding a polypeptide neuronal tryptophan hydroxylase protein is known in the art and does not make contribution over the prior art. Therefore, they all lack special technical feature.

A telephone call was made to David Saliwanchik on 10/09/2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

37 CFR 1.475 does not provide for multiple products and/or methods within a single application. Therefore, inventions of Group I - XII lack unity of invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

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